

MAY - 2 2008

Summary of Safety and Effectiveness

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: K 080911.

Submitter:

Bio-Rad Laboratories, Inc., Clinical Systems Division, 4000 Alfred Nobel Drive,
Hercules, California 94547

Phone: (510) 741-6114, Fax: (510) 741-6471

Contact Person:

Jolene Bartilson, Regulatory Affairs Representative

Device Name:

VARIANT™nbs Sickle Cell Program run on the VARIANT™nbs Newborn Screening System using Genetic Data Management (GDM) 3.0 Software

Classification Name:

Assay, Abnormal Hemoglobin, GKA

Predicate Device(s):

VARIANT™nbs Sickle Cell Program, Bio-Rad Laboratories, Inc., K051072

Intended Use:

The Bio-Rad VARIANT™nbs Sickle Cell Program is intended as a qualitative screen for the presence of hemoglobins F, A, S, D, C, and E in eluates of neonatal blood collected on filter paper by high-performance liquid chromatography (HPLC).

The Bio-Rad VARIANTnbs Sickle Cell Program is intended for Professional Use Only. For In Vitro Diagnostic Use.

The Bio-Rad VARIANTnbs Sickle Cell Program is for use only with the Bio-Rad VARIANTnbs Newborn Screening System.

Indications for Use:

The presence of hemoglobin S (HbS) in a patient blood sample is indicative of sickle cell disease or sickle cell trait. Diagnosis of sickle cell disease prior to the age of four months

treatment with penicillin has shown to decrease morbidity and mortality.¹

1. Gaston, M.H.; Verter, J.I.; Woods, G.; Pegelow, C.; Kelleher, J.; Presbury, G.; Zarkowsky, H.; Vichinsky, E.; Lye, R.; Lobel, J.S.; Diamond, S.; Holbrook, C.T.; Gill, F.M.; Ritchey, K.; Fallete, J.M. Prophylaxis With Oral Penicillin in Children With Sickle Cell Anemia: A Randomized Trial. *N. Engl. J. Med.* **1986**, *314* (25), 1593-1599.

Description of the Device:

The VARIANTnbs Newborn Screening System uses the principles of high-performance liquid chromatography (HPLC). The VARIANTnbs Sickle Cell Program is based on the chromatographic separation of hemoglobins F, A, S, D, C, and E on a cation exchange cartridge.

The new feature in this submission is the upgrade of the Genetic Data Management (GDM) software. The current software (GDM 2.01) requires Microsoft Windows NT. This product is nearing the end of its lifecycle. GDM 3.0 software is needed to transfer the GDM software to the Microsoft Windows XP Operating System.

Technical Characteristics Compare to the Predicate:

The VARIANTnbs Sickle Cell Program runs on the VARIANTnbs Newborn Screening System with GDM 3.0 and has the same basic technical characteristics as the predicate VARIANTnbs Sickle Cell Program, K051072. The technical characteristics between the two submissions are summarized in the following table:

Characteristic	<u>New Device:</u> VARIANTnbs Sickle Cell Program run on the VARIANTnbs Newborn Screening System <u>with GDM 3.0</u>	<u>Predicate Device:</u> VARIANTnbs Sickle Cell Program run on the VARIANTnbs Newborn Screening System <u>with GDM 2.01</u> (K051072)
Intended Use	The Bio-Rad VARIANT TM nbs Sickle Cell Program is intended as a qualitative screen for the presence of hemoglobins F, A, S, D, C, and E in eluates of neonatal blood collected on filter paper by high-performance liquid chromatography (HPLC). The Bio-Rad VARIANTnbs Sickle Cell Program is intended for Professional Use Only. For In Vitro Diagnostic Use. The Bio-Rad VARIANTnbs Sickle Cell Program is for use only with the Bio-Rad VARIANTnbs Newborn Screening System.	The Bio-Rad VARIANT TM nbs Sickle Cell Program is intended as a qualitative screen for the presence of hemoglobins F, A, S, D, C, and E in eluates of neonatal blood collected on filter paper by high-performance liquid chromatography (HPLC). The Bio-Rad VARIANTnbs Sickle Cell Program is intended for Professional Use Only. For In Vitro Diagnostic Use. The Bio-Rad VARIANTnbs Sickle Cell Program is for use only with the Bio-Rad VARIANTnbs Newborn Screening System.
Indications	The presence of hemoglobin S	The presence of hemoglobin S

for Use	(HbS) in a patient blood sample is indicative of sickle cell disease or sickle cell trait. Diagnosis of sickle cell disease prior to the age of four months allows for the administration of a prophylactic treatment with penicillin. Prophylactic treatment with penicillin has shown to decrease morbidity and mortality. ¹	(HbS) in a patient blood sample is indicative of sickle cell disease or sickle cell trait. Diagnosis of sickle cell disease prior to the age of four months allows for the administration of a prophylactic treatment with penicillin. Prophylactic treatment with penicillin has shown to decrease morbidity and mortality. ¹
Assay Principle	Cation exchange high-performance liquid chromatography	Cation exchange high-performance liquid chromatography
Operating System	Microsoft Windows XP	Microsoft Windows NT
ObjectStore	ObjectStore Version 6.2	ObjectStore Version 4.0
Barcode Reader	Active	Inactive
Worklist Setup	Improved to provide flexibility in the setup and a simplified daily workflow	Feature not available
XtraGrid Control	XtraGrid Control OTS Software (version 2.1.1) added to manage data represented in the Worklist Setup tables	Not included, Worklist Setup feature not available
Archive Viewer	Standalone software application that allows the user to view a database from an earlier GDM software version	Feature not available

Testing to Establish Substantial Equivalence:

Correlation:

A method correlation study between the VARIANTnbs Sickle Cell Program with GDM 3.0 and the VARIANTnbs Sickle Cell Program with GDM 2.01 was conducted at an external site to demonstrate equivalence. Samples run on the predicate device were repeated on the GDM 3.0 platform on the same day. Below is a representation of the results from this study.

Vnbs Sickle Cell Program with GDM 3.0 vs. Vnbs Sickle Cell Program with GDM 2.01

Patient Sample Type	GDM 2.01 (Predicate)	GDM 3.0 (New Device)	Agreement (%)
FA	53	53	100%

FAS	18	18	100%
FAC	6	6	100%
FAD	1	1	100%
FS	1	1	100%
Total	79	79	

Conclusion:

The modifications to the **VARIANTnbs Sickle Cell Program run on the VARIANTnbs Newborn Screening System with GDM 3.0** do not affect the intended use or indications for use of the device as described in the labeling, raise any new issues of safety or effectiveness, nor do they alter the fundamental scientific technology of the device. Therefore, we trust that the information provided in this Special 510(k) submission will support a decision of substantial equivalence of the **VARIANTnbs Sickle Cell Program run on the VARIANTnbs Newborn Screening System with GDM 3.0** to its predicate.





DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

MAY - 2 2008

Bio-Rad Laboratories, Inc.
Clinical Systems Division
C/O J.B. Bartilson
4000 Alfred Nobel Drive
Hercules, California 94547

Re: k080911

Trade/Device Name: Variant NBS Sickle Cell Program Reagent Kit, Variant NBS Newborn Screening
Regulation Number: 21 CFR 864.7415
Regulation Name: Abnormal Hemoglobin Assay
Regulatory Class: Class II
Product Code: GKA
Dated: April 1, 2008
Received: April 2, 2008

Dear J.B. Bartilson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

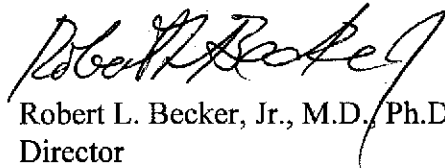
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice

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requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Robert L. Becker, Jr., M.D., Ph.D.

Director

Division of Immunology and Hematology

Office of *In Vitro* Diagnostic Device Evaluation
and Safety

Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K080911

Device Name: VARIANT™nbs Sickle Cell Program run on the VARIANT™nbs Newborn Screening System using Genetic Data Management (GDM) 3.0 Software

Indications for Use:

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The Bio-Rad VARIANT™nbs Sickle Cell Program is for use only with the Bio-Rad VARIANT™nbs Newborn Screening System.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE
OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)


Division Sign-Off

Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K080911